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HEALTH SOLUTIONS PRACTICE

AmerisourceBergen Corporation
CSRA Process Review, Phase 1
Narrative Report

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CSRA PROCESS REVIEW, PHASE 1 | FINDINGS NARRATIVE REPORT

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Project Overview and Scope

AmerisourceBergen Corporation ("Amerisource" or "ABC" or "the Company") retained FTI Consulting Inc. ("FTI") to assist the Company with an assessment of its current state processes and associated compliance activities within the Corporate Security and Regulatory Affairs ("CSRA") department. The objectives of this project were to review, map and document current state processes; identify any critical process gaps and areas for improvement; develop recommendations for process improvements and gap remediation; and scope the initial functional requirements for a technology solution(s) or technology enhancements identified as part of the recommendations. This phase of the engagement was focused on assessing the current state of the CSRA Department, with a potential second phase envisioned that will focus on the implementation of those recommendations, including the development of any technology solution(s) and/or enhancements.

FTI's work for Phase One included the following steps:
  I.   Information and Data Gathering
  II.   Map and Assess Current State Processes
  III.   Identify Findings and Recommendations

FTI's work considered the following key functional areas within CSRA's operations:

  I.   Diversion Control
  II.   Regulatory Oversight
  III.   Investigations
  IV.   Network Calls
  V.   Security Programs
  VI.   Business Continuity
  VII.   General Purpose CSRA Projects
  VIII. Project Management

The purpose of this narrative report is to document the procedures performed by our team; provide an overview of our detailed findings and observations; explain the framework of our recommendations for CSRA process improvements and gap remediation; and introduce the initial design requirements for potential technology solution(s) and/or enhancements.

A few points should be noted before summarizing the review and our findings, observations and recommendations. First, this review employed a focused scope to understand the key activities performed by the CSRA Department in order to formulate recommendations related to potential process improvements and technology enhancements. We have not conducted a deep-dive into all of the business units, functions or activities. The implementation of any recommended actions will be an iterative process that will require additional information from the business. For example, the high-level system requirements will need to be developed into a formal Business Requirements Document should the Company decide to pursue a Phase Two of this engagement.

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Second, we have not done a deep dive into all of the pharmacy and specialty operations in order to fully understand the scope of their processes and requirements. However, our recommendations contemplate further definition regarding CSRA's oversight to the non-distribution operations and a technology solution that would be scalable to incorporate additional business activities and needs.

Information and Data Gathering

During the course of our assessment, FTI gained an understanding of CSRA's systems, processes and procedures through interviews with ABC corporate and distribution center personnel and through our review of policies, procedures and other supporting documentation supplied by the CSRA team. Additionally, we visited three AmerisourceBergen Distribution Centers - one AmerisourceBergen Drug Corporation facility and two AmerisourceBergen Specialty Group facilities - which helped to further our understanding of critical CSRA processes and activities.

In considering FTI's findings and recommendations, it is important to understand the specific activities performed during our review. Information and data gathering activities included the following:

- FTI met with more than 20 AmerisourceBergen personnel through either phone or in-person discussions. A complete listing of the employees interviewed is included as Attachment 5.

- FTI conducted site visits to three distribution center facilities, which were recommended by CSRA leadership. During these visits, we met with local compliance and operations personnel and toured the facilities. The sites visited included:
    - ABDC facility in Bethlehem, Pennsylvania
    - ABSG – ASD Healthcare facility in Louisville, Kentucky
    - ABSG – ICS facility in Louisville, Kentucky

- FTI reviewed documentation related to CSRA's business operations including, but not limited to, the following:
    - CSRA organizational charts;
    - CSRA policies and procedures;
    - Sample checklists, templates and reports;
    - Systems for tracking and reporting compliance information; and
    - Project management templates and documentation.

- FTI participated in demonstrations and reviewed screen shots from existing systems and tools currently utilized by CSRA.

- FTI participated in bi-weekly status calls with the CSRA core project team.

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Map and Assess Current State Processes

In order to document our understanding of the current state processes and facilitate our assessment of said processes, FTI completed a baseline mapping of the key processes and activities relevant to each of the CSRA functional areas. The process flow diagrams reflect the key steps and communication of activities and information, as well as the critical documentation, tracking and reporting requirements for any potential matter management solution. The process flows are supported by additional procedural documentation, including a function overview that further articulates those requirements.

The process documentation packages, including a function overview, a process flow diagram, and a detailed narrative of the process steps, address the following activities and are included as Attachment 3:

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Function	Key Activities and/or Matter Types	Process Overview
I. Diversion Control		
	A) Customer Due Diligence	Diversion Control Process Flow
	B) Daily Order Investigations	Diversion Control Process Flow
	C) Ongoing Monitoring Activities	Diversion Control Process Flow
II. Regulatory Oversight - Audits		
	A) Corporate Security & Regulatory Compliance Audits	Audit Process Flow
	B) Health & Safety Program Inspections	Audit Process Flow
	C) Other Corporate CSRA Audits	Audit Process Flow
	D) DC Targeted Visits	Audit Process Flow
	E) DC Self Audits	Audit Process Flow
	F) External Agency Audits	Audit Process Flow
II. Regulatory Oversight - Compliance		
	G) Facility Licensure	Regulatory Compliance Overview
	H) State & Federal Regulatory Matrix	Regulatory Compliance Overview
	I) Compliance Monitoring Activities	Regulatory Compliance Overview
	J) Controlled Substance Requirements	Regulatory Compliance Overview
	K) Compliance Training	Regulatory Compliance Overview
	L) Customer Files	Regulatory Compliance Overview
	M) Associate Files	Regulatory Compliance Overview
	N) Committee Activities	Regulatory Compliance Overview
III. Investigations		
	A) Inbound/Outbound Product Loss	Investigations Process Flow
	B) Fraud or Forgery Issues	Investigations Process Flow
	C) Robbery or Theft	Investigations Process Flow
	D) Workplace Violence	Investigations Process Flow
	E) Company Policy Violations	Investigations Process Flow
	F) Safety Concerns	Investigations Process Flow
	G) Compliance Reports - Network & Non-Network	Investigations Process Flow
	H) Other Investigations	Investigations Process Flow
IV. Compliance Complaints (Network Calls)		
	A) Business Conduct/Ethics Issues	Network Calls Process Flow
	B) Compliance Violations	Network Calls Process Flow
	C) Employee Relations	Network Calls Process Flow
	D) Reporting of Unusual Circumstances	Network Calls Process Flow
	E) Monthly & Quarterly Reporting	Network Calls Process Flow
	F) Annual Corrective Action Log	Network Calls Process Flow
V. Security Programs		
	A) Security Inspections	Security Programs Processes
	B) Facility Security Projects	Security Programs Processes
	C) Security Systems Management	Security Programs Processes
	D) Background Checks	Security Programs Processes
VI. Business Continuity		
	A) Business Interruptions	Business Continuity Process Flow
	B) Emergency Situation	Business Continuity Process Flow
	C) Weather or Natural Disaster	Business Continuity Process Flow
	D) Incidents of Violence	Business Continuity Process Flow
	E) Loss of Communications	Business Continuity Process Flow
	F) Other Events	Business Continuity Process Flow
	G) Business Continuity Documentation	Business Continuity Process Flow
VII. Other CSRA Projects		
	A) Policies and Procedures	Document Repository
	B) New Business Ventures	Document Repository
	C) Information Requests	Document Repository
	D) Third Party Vendor Due Diligence	Document Repository
	E) Departmental Documentation	Document Repository
VIII. Project Management		
	A) Project Tracking	Project Management Overview
	B) Project Management	Project Management Overview
	C) Project Reporting	Project Management Overview

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Findings and Recommendations

FTI reviewed and evaluated CSRA's current state processes to identify existing gaps and opportunities for potential improvements. We have identified several recommendations that are designed to:

- Strengthen the effectiveness of the Company's compliance efforts;
- Increase efficiencies and promote consistency across the organization; and
- Drive more effective utilization of staff and resources.

A summary of key themes that resulted from our review is provided below, which is supplemented by a detailed inventory of our findings, observations and recommendations by functional area in the Findings Matrix provided as Attachment 1. Each recommendation in the Findings Matrix includes the rationale supporting the recommendation, the risk area(s) addressed by the recommendation and the objectives(s) achieved by implementing the recommendation. We also wanted to call attention to several macro-level recommendations related to risk management that resulted from our collective effort to understand the breadth of CSRA activities.

Significant portions of AmerisourceBergen's growth have been due to strategic acquisitions and diversification of its services, which presents cultural, technical and procedural integration challenges. In anticipation of future acquisitions, CSRA should work to develop a Compliance Integration plan that outlines the process for evaluating and integrating potential new businesses from a risk and compliance perspective. In short, senior CSRA leaders should be involved in the company's due diligence activities related to potential acquisitions in order to understand and define the scope of regulatory, security, and compliance risk a target may represent to ABC. Furthermore, CSRA – either within ABC's current acquisition integration program or outside of it to the extent one does not exist – should develop an integration plan to facilitate CSRA onboarding the regulatory, security, and other compliance functions of the target into CSRA's organization and infrastructure. This includes auditing activities, investigations, hotline reporting, P&P development, training, security protocols, and business interruption activities.

As ABC continues to grow and evolve as an organization, the CSRA team will need to adapt to the changing landscape. CSRA will not be able to rely on the tried and true procedures developed to oversee drug distribution, but will instead need to develop new protocols and identify ways to meet the increasing demands more efficiently by working smarter, not harder. Given that ABC is now a Fortune 20 company, it will be subject to increased and additional scrutiny by regulators and litigators. As such, CSRA should perform an annual risk assessment across each of the business units and reconcile the results of that risk assessment against CSRA's planned activities for the upcoming year – particularly the design of its audits and training content – to ensure key risks and/or emerging risks are addressed.

There are also several basic blocking and tackling items that CSRA needs to address related to:

- People: Defining Roles and Responsibilities (Organizationally and within CSRA);
- Processes: Addressing Inconsistent or Inefficient Processes; and
- Systems: Centralizing the Tracking and Reporting of Information.

As a general statement, most everyone we spoke with was enthusiastic about our presence and the Company's investment in an outside team to help identify areas for improvement and facilitate change. CSRA team members also seemed to appreciate having a channel through which to provide their thoughts and feedback, and were very positive about the Company and the work that CSRA does. The CSRA resources that we interacted with were very knowledgeable with respect to their subject areas, although at

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times it was challenging to nail down their specific scope of responsibilities. Because the roles and responsibilities of CSRA personnel are somewhat ill-defined, CSRA team members sometimes end up performing activities outside of their purview which detracts from the utilization of these resources. CSRA should task their Policy and Procedure Committee with completing a comprehensive review and overhaul of CSRA's policies and procedures to ensure they reflect the current roles, responsibilities and protocols. In doing so, the policies should apply broadly to all business units and the SOPs should provide the necessary guidance regarding how to handle the specific day-to-day activities for each business unit.

A large volume of work and responsibility falls to CSRA with respect to managing regulatory compliance and security activities, and some team members indicated that it is difficult to keep up with the demands. This may be because they have not received adequate training or because the team is not sufficiently staffed with the necessary resources or expertise.

For the most part, CSRA team members do not receive much in the way of formal training and instead are, in the best case, provided informal training by being paired with a more experienced resource for a brief onboarding period. As a result, some CSRA personnel feel overwhelmed by the volume of activities they are required to perform, the administrative demands of their position and the lack of direction that they are provided. CSRA needs to standardize, improve and/or develop more specific training by discipline and job function. The training also needs to address regulatory compliance activities and help CSRA personnel learn to view their activities through a risk management lens. Along the same lines, leadership should review and evaluate the competencies of the Compliance Managers and Clerks to determine where additional training, support or resources may be necessary and focus on improved tracking and managing of resource allocation and workload.

Another area that may serve to strengthen the effectiveness of CSRA is to better define CSRA's position within the organization. Perhaps most importantly, CSRA needs to define its role in providing oversight to the specialty businesses and non-distribution services. Although we did not conduct a detailed assessment of each business unit, we suspect there is limited visibility, connectivity and oversight to certain subsidiary businesses and there appears to be disconnect between the corporate teams in Valley Forge and Frisco. There is also an impression that the Specialty Group and sister companies do not recognize CSRA as an authoritative body and do not have any meaningful contact or communications with CSRA. Even for those business units where there is some CSRA involvement, CSRA may not be focused on the risks specific to each organization because CSRA protocols are deeply seeded in monitoring the drug distribution centers. Organizationally, ABC needs to establish and define the scope of CSRA's organizational responsibilities, reconcile those activities to existing standards and practices, identify and mitigate any gaps, and ensure adequate communication, oversight and reporting.   In addition, CSRA needs to change its mindset when engaging with business units that provide non-distribution services, because the same standards won't necessarily apply. As such, CSRA should conduct a "deep-dive" into scoping the risk and activities relevant to each of the additional business units.

Similarly, establishing the delineation of regulatory and compliance responsibilities and defining the rules of engagement by and between CSRA and other corporate departments that are involved with "compliance activities" is critical in terms of defining ABC's risk management program. During our discussions, and even during our pre-planning for the project, there was recurring mention of other areas of the organization with compliance responsibilities. While that is a good sign that the infrastructure is in place to perform compliance related activities, it does indicate – especially with the run of acquisitions – that compliance responsibilities are too diffuse or their ownership unclear. That creates the potential that compliance activities are not occurring because "left hand doesn't know what the right hand is doing", or because

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there's an assumption that someone else in the organization is taking care of it. Regulatory and compliance activities need to be documented in a Regulatory and Compliance Program Plan which is reviewed and refreshed annually by compliance leadership, with input from senior management. These practices work together to serve as the foundation for ensuring the organization is maintaining and evolving its regulatory infrastructure to respond to changes in the business timely and appropriately.

There is a sense that some compliance and other corporate initiatives do not fully consider the burden that these organizational changes put on the compliance resources. For example, the centralization of certain support functions such as Customer Care and Human Resources did not adequately contemplate the downstream effect in terms of delays and inconsistent information provided to the local Compliance Managers. Not involving CSRA in operational initiatives limits the ability to head off issues that may ultimately present compliance challenges or concerns.

CSRA is very reactive to situations, with certain team members describing their job as "constantly putting out fires." Being in a perpetual state of reacting to situations makes it difficult to implement and sustain organizational improvements and prevents resources from focusing on assigned projects. CSRA should strive to be more proactive in their activities, which starts by better defining roles, responsibilities and procedures and getting away from the mentality that "this is how we've always done it." As ABC continues to grow and expand into new service offerings, the demands on CSRA will continue to increase and will require team members to be proactive in their work.

CSRA appears to have many initiatives underway to strengthen the efficacy of the group, but remains largely reactive to issues and requests. In light of the fact that efforts are in progress, we recommend leveraging the established committees, particularly to address some big ticket items such as improving policies and procedures, defining roles and responsibilities and enhancing training. The existing committees are as follows: Audit Committee; Policy Committee; Standardization Committee; Training Committee; and Conference Planning Committee.

For the most part, CSRA has good processes in place but struggles with documenting and providing visibility to those efforts. The organization suffers from decentralized and segmented tracking and documentation of information and activities, which results in limited reporting and tracking of workload, as well as a lack of access to timely and comprehensive information across CSRA. The risk here is management by intuition, rather than having the data and analysis to support strategic decisions and resource planning.

CSRA personnel have developed personal tools and logs for the tracking of matters and issues, but there is a lack of clear policy guidance on determining what should be elevated to the corporate levels or the appropriate channels or departments through which issues should be reported. Automating the process to allow for electronic submission and tracking of complaints, issues and incidents will both streamline the reporting process and allow for more systematic investigation, tracking and resolution. Similarly, creating electronic versions of forms, checklists and reports that can be completed online will improve efficiencies, reduce duplicative efforts and provide a more robust database of information to be analyzed and reported.

Across all CSRA functions, and most particularly at the facilities, there is a large volume of paperwork to maintain, to the point that some CSRA personnel view their role as administrative rather than regulatory. Certain DEA Forms and other required documents will continue to require manual completion and physical storage. However, there are a number of forms and checklists that can be streamlined and/or transitioned to electronic form. Where possible, CSRA should eliminate the need to record information on paper forms that then need to be entered into an electronic repository. This may require an investment in tablets or

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laptops for CSRA resources, but the bottom line is that a better balance could be struck such that high standards of compliance are maintained while the administrative burden of paper processes on CSRA resources is lessened.

Many of CSRA's challenges stem from inefficient and time consuming manual processes and activity tracking that could benefit from improved technology solutions. In fact, CSRA personnel were consistent in stating that the lack of an integrated matter management system creates significant process challenges, particularly as it relates to managing, tracking, reporting, and documenting department activities and workflows. Implementing a centralized and comprehensive system and repository to manage regulatory compliance and security requirements where different constituents across the organization can enter and access information, supported by standardized and automated reports, dashboards and notifications, would significantly enhance some of the highly manual activities and provide better oversight to CSRA's activities and results. Some of the key benefits of such a matter management solution would include:

- Integrated and centralized solution that provides a holistic view to all CSRA functions and activities
- Customizable and scalable platform that can grow with the business
- Improved data capture at the point of intake
- Streamlined and automated workflows to drive consistencies and reduce costs
- Utilization of data in order to identify and mitigate risks more proactively
- Shared access to information and documentation
- Oversight to CSRA processes through management reporting
- Platform for increased and consistent communications

The Process Documentation packages provided as Attachment 2 include an initial inventory of the representative matter management considerations for each function area, including:

- Key Activities and/or Matter Types to be documented
- Reference Documents and Guidelines to make available
- Documents, Forms and Checklists to be completed
- Critical Tracking and Reporting requirements

The Findings Matrix included as Attachment 1 provides specific findings and recommendations related to each of the CSRA Functional Areas that were reviewed. We have provided below some overall impressions and commentary regarding each of those Functional Areas below:

I. Diversion Control

CSRA is responsible for ABC's Diversion Control Program, which is designed to prevent and detect the diversion of controlled substances and listed chemicals. The CSRA Diversion Control Team is in the process of implementing a number of process and system improvements, so we've limited our comments on this function to a couple of key observations and risk areas.

As part of the Diversion Control process, orders of controlled substances and listed chemicals are subject to review by the electronic Order Monitoring Program. Orders that exceed established parameters are held in the system and identified for investigation prior to adjudication of the order. ABC does not have a policy to determine which associate(s) at the distribution center are responsible for reviewing orders. Although all associates who have access to the OMP system are required to be trained in reviewing orders, there is no

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consistency with respect to who is reviewing these orders. This presents a significant risk area because the company needs to be compliant with DEA regulations and able to explain and defend their decisions.

In addition, centrally tracking and documenting the customer due diligence files and ongoing monitoring activities will allow for better access to information, better ability to respond to requests for information and more complete management oversight.

II. Regulatory Oversight

CSRA provides regulatory compliance and security assistance to all ABC distribution centers and other business units. Performing on-site audits is a primary function of CSRA. The current audit tools are very comprehensive, but also manual and time consuming to complete. Adjustments to CSRA's approach to auditing may help to better align the process with the Company's risk areas and business structure while making audits more efficient and effective. Accordingly, we have identified several recommendations for audit program adjustments and system improvements related to the testing, analysis and reporting that focus on better and timelier collection and utilization of audit data and information.

There are a host of additional responsibilities and activities related to ensuring regulatory compliance that fall to the CSRA team. These activities range from maintaining facility licensure to managing regulatory reporting obligations to ensuring all associates have received requisite compliance training. With these responsibilities comes the need to complete and maintain a great deal of forms, checklists and documentation, as well as numerous tracking and reporting responsibilities, which can all be addressed through a more comprehensive Matter Management Solution.

III. Investigations

CSRA is responsible for conducting investigations in order to respond to reports of incidents that relate to the internal security, safety and regulatory compliance of the Company or affect its personnel, property, facilities or proprietary interests. There are established processes for conducting investigations, although there are some inconsistencies in defining the roles and responsibilities for handling incidents, incomplete guidance with regard to documenting investigations and a lack of formal training for investigators.

Our recommendations in this area primarily address the specific business and functionality requirements that should be considered in the development of a single, integrated solution and improvements that will assist with the tracking, reporting and monitoring of investigatory activities. Coupled with improved governance around the processes and responsibilities, a better technology solution will help to drive consistencies in conducting investigations, ensure outcomes of investigations are adequately documented, and provide better visibility and oversight to management through centralized and automated tracking, trending and reporting.

IV. Compliance Complaints (Network Calls)

CSRA is responsible for responding to reports of potential compliance violations and alleged wrongdoing received through the Compliance Incident Reporting program ("The Network"). Our recommendations in

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this area focus less on the process for receiving and addressing Network Calls and more on the efficiencies that can be gained through a better technology solution that would allow for more automated work flows, activity tracking and management reporting.

V.   Security Programs

CSRA is responsible for physical security systems, programs and activities at all ABC facilities. The scope of activities that fall within the purview of CSRA's Security Services team range from performing security inspections, overseeing the security systems and programs installed at ABC facilities, and monitoring the background screening process to ensure hiring practices are compliant with Company policies. With respect to the background screening process and other security programs, a technology solution would offer better controls around those activities, as well as potentially better utilization of resources through more automated tracking and reporting.

VI. Business Continuity

CSRA is responsible for the oversight of the Company's Business Continuity Program, which requires that all business units have a plan that outlines the standards, action and communications associated with responding to anticipated or actual business interruptions. Our recommendations in this area focus less on the process for addressing business interruptions, which may require further study, and more on the efficiencies that can be gained through a better technology solution that would allow for automated work flows and reporting.

VII. General Purpose CSRA Projects

At any point in time, there are a number of other projects that fall within the purview of CSRA and need to be documented and tracked. Documents and information managed or created by any CSRA projects would flow into and be maintained within in the Matter Management Solution.

There are additional regulatory oversight and compliance activities required to be performed by specific business units or subsidiaries, depending on the services offered. Although we have not developed a full inventory of these activities across each of the business units, any Matter Management Solution would contemplate the ability to incorporate the documentation and tracking of such activities. Some of these additional activities might include, but certainly are not limited to, the following:

- Quality Management and Metrics
- Accreditation and Licensure
- Adverse Event Reporting
- HIPAA Disclosures

VIII.   Project Management

CSRA recently added a Project Manager to the team who is responsible for managing, tracking and reporting on projects and activities. In considering the Project Management function, we have conducted a

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preliminary inventory of the different forms and types of project documents that would be maintained within a Matter Management Solution.

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Listing of Attachments

Attachment 1. Findings Matrix
Attachment 2. Matter Management Solution Requirements
Attachment 3. Functional Area Process Documentation
Attachment 4. CSRA Business Unit Oversight Document
Attachment 5. Personnel Interviewed

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